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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,809	07/23/2003	Robert Cafferata	PA1309 CIP (2650/52)	7768

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Medtronic Vascular, Inc.
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EXAMINER	
STIGELL, THEODORE J	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,809	CAFFERATA, ROBERT	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bagaoisan et al. (6,152,909). See Figure 9 and the respective portions of the specification. Bagaoisan et al. clearly disclose a system that includes a rupture device (52) that can be inserted into a blood vessel past an occlusion. A second therapy catheter, which can also be considered a rupture device, is then inserted and can include an angioplasty balloon, a cutting or shaving device, a thermal balloon, a laser device (cauterizing device), or an ultrasound device. The rupture device can also include the use of a stent and various thrombolytic agents. See column 7, lines 45-62. The system also includes a capture device (60), which can also include a distal protection filter or balloon, to capture the emboli from the fractured plaque. See column 6, lines 13-29. The capture device can also be an aspiration catheter as is shown in Figure 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. (6,152,909) in view of Campbell et al. (6,245,026). Bagaoisan et al. disclose a system of treating a vulnerable plaque that includes all of the limitations as recited in claim 20. Bagaoisan et al. do not teach to include a thermal sensor to detect the location of vulnerable plaque. Campbell et al. disclose a system of detecting a vulnerable plaque by using a catheter with a thermal sensor. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Bagaoisan et al. with the catheter of Campbell et al. to make a more accurate and effective system of locating and removing vulnerable plaque in a blood vessel.

Double Patenting

It is acknowledged that conflicting claims 20-27 in copending Application No. 10/427,680 have been withdrawn and therefore the double patenting rejection for the instant application has been withdrawn.

Response to Arguments

Applicant's arguments filed November 28, 2005 have been fully considered but they are not persuasive. The Applicant has argued that 1) Bagaoisan (6,152,909) does not teach or suggest a system for treating a vulnerable plaque but instead teaches a system of treating partial or complete occlusions, 2) Bagaoisan does not teach a system for treating vulnerable plaque that includes a stent operably coupled to the rupture device, 3) Bagaoisan does not teach a system for treating vulnerable plaque that includes a cauterizing device that cauterizes the plaque, and 4) Bagaoisan does not teach a detection device or a thermal sensor.

In response to applicant's first argument, the recitation "for treating a vulnerable plaque associated with a blood vessel of a patient" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Also in response to applicant's first argument that Bagaoisan does not disclose a rupture device that ruptures a fibrous cap of the vulnerable plaque, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The rupture device (52) of Bagaoisan seems

capable of rupturing a vulnerable plaque if it is moved over or rotated around the area of a vulnerable plaque.

In response to Applicant's second argument that Bagaoisan does not teach a stent operably coupled to the rupture device, the Examiner respectfully disagrees. In regards to Figure 9, Bagaoisan describes a method in which a guidewire (50) with the rupture device (52) is moved past the site of the occlusion and then a therapy catheter which can include a catheter that delivers a stent (column 15, lines 7-34) is delivered to the occlusion. It is the position of the Examiner that the second catheter (therapy catheter) is also considered a rupture device. Therefore, Bagaoisan does disclose a catheter operably coupled to the rupture device.

In response to Applicant's third argument that Bagaoisan does not teach a system including a cauterizing device, the Examiner respectfully disagrees. In column 15, lines 25-26 Bagaoisan discloses the use of a laser to ablate an occlusion. It is the Examiner's position that a laser can be considered as a type of cauterizing device.

In response to the Applicant's fourth argument that Bagaoisan does not disclose a detection device comprising a thermal sensor, the Examiner agrees. However, the Examiner has never stated that Bagaoisan has taught this limitation and therefore has combined the Bagaoisan reference with the Campbell reference. It is the position of the Examiner that Bagaoisan does teach all of the limitations in independent claim 20 and that it is proper to combine the Campbell reference to meet the limitations of claims 23-24.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Theodore J. Stigell